CLINICAL RESEARCH CURRICULUM AWARD

RELEASE DATE: July 1, 2003

RFA: HL-04-004

National Institutes of Health (NIH)

CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER(S): 93.837, 93.838, 93.839

LETTER OF INTENT RECEIPT DATE: December 16, 2003

APPLICATION RECEIPT DATE: January 16, 2004

THIS RFA CONTAINS THE FOLLOWING INFORMATION:

PURPOSE OF THIS RFA

The National Institutes of Health (NIH) invites educational and research institutions to apply for the Clinical Research Curriculum Award (CRCA or K30). This program is supported by all NIH Institutes and Centers. The initial and competing renewal awards will be for five years each. Applications in response to this RFA may be either new or competitive renewals.

The CRCA is an award to institutions and addresses, in part, the NIH's commitment to improve the quality of training in clinical research. The NIH recognizes that highly

trained clinical researchers are needed in order to capitalize on the many profound developments and discoveries in basic science and to translate them to clinical settings. This RFA is intended to stimulate the inclusion of high-quality, multidisciplinary didactic training as part of the career development of clinical investigators. The CRCA supports the development and/or improvement of core courses designed as in-depth instruction in the fundamental skills, methodology, and theory necessary for the well- trained, independent, clinical researcher. While many NIH programs support research experiences for new clinicians, not all of these trainees have the opportunity to receive formal course work in the design of clinical research projects, hypothesis development, biostatistics, epidemiology, disease mechanisms, medical technology, human genetics, and the legal, ethical and regulatory issues related to clinical research. This award is intended to support the development of new didactic programs in clinical research at institutions that do not currently offer such programs and, in institutions with existing didactic programs in clinical research, to support and expand programs or to improve the quality of instruction. The goal of this program is to improve the training of the participants, so that upon completion of their training, they can more effectively compete for research funding.

For the purpose of this award, clinical research includes: patient-oriented research, epidemiologic and behavioral studies, and outcomes or health services research. The NIH defines patient-oriented research as research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) that requires direct interactions with human subjects. Patient-oriented research includes study of the disease, therapeutic interventions and clinical trials.

TRAINING OBJECTIVES

Background

This RFA seeks to continue the K30 program in order to attract talented individuals to the challenges of clinical research and to provide them with the critical skills that are needed. There is a core of knowledge and skills common to all areas of clinical research that should form the foundation of clinical research training. These skills will also serve to improve the ability of new clinical investigators to develop hypotheses and draft sound research proposals for support. This initiative is consistent with the recommendations of the NIH Director's Panel on Clinical Research (http://www.nih.gov/news/crp/97report/index.htm), and those from the Institute of Medicine Committee on Addressing Career Paths for Clinical Research.

Goals and Scope

The objective of this RFA is to improve the quality of clinical research training by providing didactic courses in the fundamental skills needed for clinical research. The long-term goal is to produce clinical researchers who are competitive in seeking research support and are knowledgeable about the complex issues associated with conducting sound clinical research. This RFA is open to educational and research institutions that do

not currently provide such a didactic program, as well as to those that have well-established clinical research training programs. This award provides resources to allow institutions to conduct a comprehensive clinical research curriculum. A curriculum for each group of participants should be designed for two years, and the applicant institutions should justify the period and describe plans for enrolling a cohort of participants each year. The planning, direction, and execution of the instructional program will be the responsibility of the Program Director and the awardee institution, but must be consistent with the goals of the CRCA. The curriculum must span a variety of fields of research and encompass a broad range of clinical scientists who are interested in the mechanisms of human disease, the genetics of complex disorders, and therapeutic interventions. The core curriculum is to include an array of clinical research-related topics of general interest such as biostatistics, bioethics, clinical trials design, observational study design, Federal policies and regulations that address research with human subjects (e.g., 45CFR46, FDA, INDs, inclusion of women and minorities as well as children in clinical research projects), scientific writing for publication, and preparation of competitive grant applications. The program may also include bioinformatics, human genetics, pharmacokinetics, medical applications of new technologies, specialized courses in epidemiology, the study of health disparities and other relevant fields. The scope of the curriculum can be flexible to meet the needs of the institution. Inclusion of interdisciplinary approaches is strongly encouraged.

Institutions may propose providing support for candidates to earn a master's or a doctoral degree in a relevant area. The proposed program should also have the flexibility to accommodate participants with different levels of experience.

Individuals participating in the program should demonstrate a potential for the pursuit of innovative clinical research as a major focus in their career plan, and plan to enter into a long-term clinical research career. Institutions or consortia applying for an award must be able to demonstrate a historical record of attracting and producing such individuals. If not already ongoing, new programs should have the faculty and specific plans for recruiting participants to enter the didactic program.

MECHANISM OF SUPPORT

This RFA will use the NIH K30 award mechanism. As an applicant you will be solely responsible for planning, directing, and executing the proposed project. The total project period for an application submitted in response to this RFA is five years. The anticipated award dates are between June 1 and September 30, 2005. Future years of support will depend on evaluation of the program.

This RFA uses just-in-time concepts. It does not use modular budgeting format.

FUNDS AVAILABLE

The NIH intends to commit approximately $15 million per year for a total of five years starting in FY 05 to fund about 50 new and competitive continuation grants in response to this RFA. An applicant should request a project period of five years and a budget for total costs of $300,000 per year. Although the financial plans of the NIH provide support for this program, awards are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.

ELIGIBLE INSTITUTIONS

o For-profit or non-profit domestic, non-Federal organizations
o Public or private domestic institutions, such as universities, colleges, and hospitals.

Foreign institutions are not eligible to apply.

Applications will be accepted from organizations that have strong, well-established clinical research and/or clinical research training programs. The applicant institution must have a highly trained faculty that is active in clinical research, as evidenced by current research support, and have the commitment and capability to provide the core curriculum to individuals in the development of a clinical research career. Institutions with a substantial clinical research portfolio along with a sufficiently large group of individuals in some aspect of clinical research training and career development are eligible to apply. An institution may submit only one application, either new or competitive renewal. This award is open to both current K30 recipients and those without a K30 award. Applicants are encouraged to develop consortia in a common geographic location to enhance the depth of their faculty and participant pool, and/or to improve the quality of the educational experience.

INDIVIDUALS ELIGIBLE TO BECOME PROGRAM DIRECTORS

The Program Director should possess the clinical research expertise, leadership and administrative capabilities required to coordinate and supervise an interdisciplinary didactic program of this scope. The Director should also be experienced in the design and management of programs for the development of clinical investigators, and should be able to demonstrate a superior record of preparing individuals for independent clinical research. The Program Director should be the role model for the participants. He or she should be personally engaged in clinical research as well as in the mentoring of new investigators. A minimum of 20% of the Program Director's effort is required. (Combined Program Director and Co-Director's effort should be at least 40%.) Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply for NIH programs.

INDIVIDUALS ELIGIBLE TO BECOME PROGRAM FACULTY

Faculty involved in the CRCA should have a record of developing and teaching the type of curriculum required under this award. Generally, faculty will also be accomplished investigators. The faculty records of teaching and mentoring, as well as the percent of faculty effort planned for the courses should be described. Program faculty members from under-represented minority groups or with disabilities are encouraged.

INDIVIDUALS ELIGIBLE TO BECOME PROGRAM PARTICIPANTS/ TRAINEES

All participants must be U.S. citizens, non-citizen nationals or lawfully admitted permanent residents of the U.S. Participants may include those with the following degrees: M.D., D.D.S., D.M.D., D.O., D.C., O.D., N.D. (Doctor of Naturopathy), doctorally prepared nurses, Ph.D. with clinical responsibilities, and others who could benefit from a core curriculum for clinical research. Because clinical research is multidisciplinary, participants in this program should represent diverse academic backgrounds. Interactions during the early years of career development may serve to enhance the team approach necessary to meet the multidisciplinary challenges of clinical research.

Participants may include individuals with NIH support (F32, T32, Ks, etc.) as well as those with non-NIH support for training and career development.

The National Heart, Lung, and Blood Institute will administer this program for the NIH. All potential applicants are strongly advised to contact the NHLBI/NIH staff listed below to discuss their eligibility and the specific provisions of this award.

In all respects, the NIH remains strongly committed to increasing the participation of individuals from underrepresented minority groups and individuals with disabilities in biomedical and behavioral research. The following groups have been identified as underrepresented in biomedical and behavioral research nationally: African Americans, Hispanic Americans, Native Americans, Alaska Natives, and Pacific Islanders. Applicants must describe their program plans and efforts to recruit such individuals, as well as their success in the recruitment, retention, and graduation of these individuals. All applications must contain plans to demonstrate commitment and proactive recruitment efforts.

ELIGIBLE COMPETING CONTINUATION APPLICATIONS

Competing continuation applications must propose and justify substantial changes/modifications/improvements in the K30 curriculum developed during the prior funding period.

SPECIAL REQUIREMENTS

Program: The program award provides five years of support. Future years of support will depend on an evaluation of the success of the program. The award will support a high-quality didactic program in the fundamentals needed for independent clinical research. Institutions applying for competitive renewals of existing awards must describe the existing program and include plans for enhancement of the programs. New applicants must provide a detailed description of and justification for the program including courses offered, frequency and scheduled times of classes, selection criteria for participants entering the program, and target goal of enrollment into the program. Both new programs and new components of existing programs must be operational within one year of the award.

Environment: The institution must have high-quality clinical research and qualified faculty in clinical research. The proposed faculty should be actively engaged in the design and conduct of such research, and also have demonstrated a successful record in obtaining peer reviewed federal and non-federal funding for such activities. The institution must develop an innovative, multidisciplinary program to maximize the available research and educational resources. Applicant institutions must describe the pool of participants and must demonstrate experience in preparing individuals for careers in clinical research. Because mentoring, as well as didactic coursework, is an integral part of successful training, existing and planned mentoring activities should be described.

Advisory Committee: The Program Director must have or establish an Advisory Committee for this program to provide ongoing assessment and monitoring. Clinical and basic science departments participating in this program should be represented on the committee. The committee's responsibilities might include: selecting participants, evaluating each participant's progress, and monitoring the overall effectiveness of the didactic program and updating it as needed. A detailed description should be provided of the committee's composition, function, and organizational structure.

Assessment: Plans for assessment of the Program by the Advisory Committee should be described.

Program Evaluation: The success of the overall CRCA program, as well as the success of individual awards will be evaluated. As part of this evaluation, NIH will request, as a component of the Annual Progress Report of the grant, tables containing the number of trainees, by year; number completing the program; number receiving degrees as a result of the program; number of trainees submitting applications for research funding; number receiving research funding, and number of mentors participating in the program. An assessment of the quality of the didactic training and of the mentoring will be requested, as will a description of the overall effect of the program on the institutional culture toward clinical research.

Allowable Costs: Allowable costs may include personnel (support for the Program Director, faculty, and administrative support), supplies, travel, honoraria and per diem for outside speakers, seminars, development of course materials, consultants, and other costs, such as printing, telephone, audio-visual, postage, recruitment materials, and computer software.

The compensation for the Program Director must not exceed the actual institutional salary rates for the effort being devoted to the CRCA. In addition, salary rates must not currently exceed an annual salary level of $171,900 plus fringe benefits. The Program Director must devote at least 20% effort and no greater than 50% effort to this award, and may also be a principal investigator on other research awards.

Funds may not be requested to directly support the individual trainees. Their activities are expected to be supported by other Federal or non-Federal sources. However, in some circumstances, and for trainees supported by non-governmental funds, tuition is an allowable expense.

Annual meetings of Program Directors and other staff members to exchange information about effective approaches in the training of new clinical investigators, including the sharing of course materials, have been initiated and will be continued. Funds to support travel of the Program Director and another staff person to these meetings should be included. For budgeting purposes, assume that the meetings will be held in the Washington, D.C. area.

WHERE TO SEND INQUIRIES

We encourage inquiries concerning this RFA and welcome the opportunity to answer questions from potential applicants. Inquiries may fall into three areas: programmatic, peer review, and financial or grants management issues:

o Direct your questions about programmatic issues to:

Lawrence Friedman, M.D.
National Heart, Lung, and Blood Institute
Building 31, Room 5A03
Bethesda, MD 20892-2482
Telephone: (301) 496-9899
FAX: (301) 402-1056
Email: lawrence_friedman@nih.gov

Belinda Seto, Ph.D.
Office of Extramural Research
National Institutes of Health
Building 1, Room 252
Bethesda, MD 20892-0162
Telephone: (301) 402-9128

FAX: (301) 402-2642
Email: setob@od1tm1.od.nih.gov

Direct inquiries regarding review issues to:

Anne Clark, Ph.D.
Chief, Review Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 7214
Bethesda, MD 20892-7924
Bethesda, MD 20817 (for express/courier service)
Telephone: (301) 435-0270
FAX: (301) 480-0730
Email: clarka@nhlbi.nih.gov

Direct inquiries regarding fiscal matters to:

Owen Bobbitt
Grants Operations Branch
Division of Extramural Affairs
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 7134
Bethesda, MD 20892-7926
Telephone: (301) 435-0270
FAX: (301) 480-0422
Email: ob5i@nih.gov

LETTER OF INTENT

Prospective applicants are asked to submit a letter of intent that includes the following information:

o Descriptive title of the proposed research
o Name, address, and telephone number of the Principal Investigator
o Names of other key personnel
o Participating institutions
o Number and title of this RFA

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

The letter of intent is to be sent by the date listed at the beginning of this document. The letter of intent should be sent to Anne Clark, Ph.D. at the address listed under WHERE TO SEND INQUIRIES.

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive format. For further assistance contact GrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

It is strongly recommended that prospective applicants contact the staff person listed under INQUIRIES early in the planning phase of the CRCA application. Such contact will help ensure that applications are responsive to the overall intent of this award.

The application must address the following issues:

1. Didactic Courses: Describe the content of the proposed courses and their potential benefits to the participants. Describe how continuation and/or expansion of an existing program or development of a new program will enhance clinical research training at the institution.

2. Institutional Commitment: Provide information establishing the commitment of the applicant institution, the Program Director, and the faculty to providing didactic and mentoring experiences.

3. Career Development Plans: Describe how the activities supported by this award will advance the career development plans for prospective participants.

4. Availability of Participants: Describe the pool of potential participants including information about the types of prior clinical and research training. Describe the composition of the selection committee and the criteria to be used for selection. Provide demographic data and the number of individuals participating in current training programs, e.g., T32, K12, K08, F32, K23, K24, and others eligible for this program. This information will be evaluated to determine whether a sufficient number of participants will be available for the CRCA.

5. Research Environment: Describe to the extent possible the types of research experiences that will be available to the participants upon completion of the didactic training supported by the CRCA.

6. Instruction in the Responsible Conduct of Research: Applicants must include plans for instruction in the responsible conduct of research, including the rationale, subject matter, appropriateness, format, frequency and duration of instruction, and the amount and nature of faculty participation. No award will be made if an application lacks this component.

7. Program Effectiveness: The applicant institution is to include a component to assess the effectiveness of the proposed curriculum, including benchmarks against which success of the program can be measured. Applicants submitting renewal applications must include an account of the career outcomes of the participants who received training supported by the CRCA. In a text or table format, include participants' names, times spent in this program, positions held, research involvement, publications, major accomplishments, current status of participants supported by this program and other evidence that the institution is meeting the objectives described above.

USING THE RFA LABEL: The RFA label available in the PHS 398 (rev. 5/2001) application form must be affixed to the bottom of the face page of the application. Type the RFA number on the label. Failure to use this label could result in delayed processing of the application such that it may not reach the review committee in time for review. In addition, the RFA title and number must be typed on line 2 of the face page of the application form and the YES box must be marked. The RFA label is also available at: http://grants.nih.gov/grants/funding/phs398/label-bk.pdf.

SENDING AN APPLICATION TO THE NIH: Submit a signed, typewritten original of the application, including the Checklist, and three signed, photocopies, in one package to:

Center For Scientific Review
National Institutes Of Health
6701 Rockledge Drive, Room 1040, MSC 7710
Bethesda, MD 20892-7710
Bethesda, MD 20817 (for express/courier service)

At the time of submission, two additional copies of the application plus all five collated sets of appendix material must be sent to Anne Clark, Ph.D. at the address listed under WHERE TO SEND INQUIRIES.

APPLICATION PROCESSING: Applications must be received on or before the application receipt date listed in the heading of this RFA. If an application is received after that date, it will be returned to the applicant without review.

Although there is no immediate acknowledgement of the receipt of an application, applicants are generally notified of the review and funding assignment within 8 weeks.

The Center for Scientific Review (CSR) will not accept any application in response to this RFA that is essentially the same as one currently pending initial review, unless the applicant withdraws the pending application. However, when a previously unfunded application, originally submitted as an investigator-initiated application, is to be submitted in response to an RFA, it is to be prepared as a NEW application. That is the application for the RFA must not include an Introduction describing the changes and improvements made, and the text must not be marked to indicate the changes. While the

investigator may still benefit from the previous review, the RFA application is not to state explicitly how.

PEER REVIEW PROCESS

Upon receipt, applications will be reviewed for completeness by the CSR and responsiveness by the (IC). Incomplete and/or non-responsive applications will be returned to the applicant without further consideration.

Applications that are complete and responsive to the RFA will be evaluated for scientific and technical merit by an appropriate peer review group convened by the National Heart, Lung, and Blood Institute in accordance with the review criteria stated below. As part of the initial merit review, all applications will:

o Receive a written critique
o Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score
o Receive a second level review by an appropriate national advisory council or board.

REVIEW CRITERIA

The scientific review group will address and consider each of the following criteria in assigning your application's overall score:

- Quality of the content of courses and adequacy of the syllabus.

- Clinical, scientific and administrative leadership qualifications and experience of the Program Director.

- Qualifications of the faculty: portfolio of on-going funded projects, publications and training experience in clinical research.

- Criteria for selecting participants, publicizing the availability of the program to potential participants, and demonstration of a sufficient number of high quality participants.

- Adequacy and availability of any necessary institutional facilities and resources.

- Effectiveness of plans for program oversight and on-going assessment, including adequacy of the membership and functions of the program Advisory Committee.

- Strength of the institutional commitment to the support of the K30 curriculum after the end of the funding period of the K30 grant.

The additional review criteria for competing continuation applications for the Clinical Research Curriculum Award will include:

- Track record of the previous K30 program in achieving its objectives.
- Effectiveness of the developed K30 curriculum.
- Impact of the K30 program on the institutional culture.
- The justification for continued support of the K30 program, i.e. substantial changes/modifications /improvements in the K30 curriculum developed during the prior funding period.

ADDITIONAL CONSIDERATIONS

BUDGET: The reasonableness of the requested budget for the proposed didactic program.

RECEIPT AND REVIEW SCHEDULE

Letter of Intent Receipt Date: December 16, 2003
Application Receipt Date: January 16, 2004
Peer Review Date: June, 2004
Council Review: October, 2004
Earliest Anticipated Start Date: June 1, 2005

AWARD CRITERIA

Applications will compete for available funds with those submitted and reviewed in response to this RFA. This is a trans-NIH program that is being administered and managed by the National Heart, Lung, and Blood Institute. An NIH Coordinating Committee has been established to participate in all phases of this program. Funding decisions will be based on the recommendations of the initial review group, the National Heart, Lung, and Blood Advisory Council and the NIH Coordinating Committee regarding scientific and programmatic merit as well as the availability of funds.

REQUIRED FEDERAL CITATIONS

HUMAN SUBJECTS PROTECTION: Federal regulations (45CFR46) require that applications and proposals involving human subjects must be evaluated with reference to the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm

MONITORING PLAN AND DATA AND SAFETY MONITORING BOARD: Research components involving Phase I and II clinical trials must include provisions for assessment of patient eligibility and status, rigorous data management, quality assurance, and auditing procedures. In addition, it is NIH policy that all clinical trials require data and safety monitoring, with the method and degree of monitoring being commensurate

with the risks (NIH Policy for Data and Safety Monitoring, NIH Guide for Grants and Contracts, June 12, 1998: http://grants.nih.gov/grants/guide/notice-files/not98-084.html).

INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH: It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects unless a clear and compelling justification is provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing clinical research should read the "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research - Amended, October, 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html);
a complete copy of the updated Guidelines are available at
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.
The amended policy incorporates: the use of an NIH definition of clinical research; updated racial and ethnic categories in compliance with the new OMB standards; clarification of language governing NIH-defined Phase III clinical trials consistent with the new PHS Form 398; and updated roles and responsibilities of NIH staff and the extramural community. The policy continues to require for all NIH-defined Phase III clinical trials that: a) all applications or proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) investigators must report annual accrual and progress in conducting analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:
The NIH maintains a policy that children (i.e., individuals under the age of 21) must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific and ethical reasons not to include them. This policy applies to all initial (Type 1) applications submitted for receipt dates after October 1, 1998.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines" on the inclusion of children as participants in research involving human subjects that is available at
http://grants.nih.gov/grants/funding/children/children.htm

REQUIRED EDUCATION ON THE PROTECTION OF HUMAN SUBJECT PARTICIPANTS: NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for research involving human subjects. You will find this policy announcement in the NIH Guide for Grants and Contracts Announcement, dated June 5, 2000, at
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

HUMAN EMBRYONIC STEM CELLS (hESC): Criteria for federal funding of research on hESCs can be found at http://stemcells.nih.gov/index.asp and at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. Only research using hESC lines that are registered in the NIH Human Embryonic Stem Cell Registry will be eligible for Federal funding (see http://escr.nih.gov). It is the responsibility of the applicant to provide the official NIH identifier(s) for the hESC line(s) to be used in the proposed research. Applications that do not provide this information will be returned without review.

PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMATION ACT: The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. NIH has provided guidance at http://grants.nih.gov/grants/policy/a110/a110_guidance_dec1999.htm.

Applicants may wish to place data collected under this PA in a public archive, which can provide protections for the data and manage the distribution for an indefinite period of time. If so, the application should include a description of the archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

STANDARDS FOR PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION: The Department of Health and Human Services (DHHS) issued final modification to the "Standards for Privacy of Individually Identifiable Health Information", the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information, and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about applicability and implementation of the Privacy Rule reside with the researcher and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information on the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, funding, and progress monitoring of grants, cooperative agreements, and research contracts can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

URLs IN NIH GRANT APPLICATIONS OR APPENDICES: All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, Internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Furthermore, we caution reviewers that their anonymity may be compromised when they directly access an Internet site.

HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This RFA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

AUTHORITY AND REGULATIONS: This program is described in the Catalog of Federal Domestic Assistance at http://www.cfda.gov/ and is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review. Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement. The NIH Grants Policy Statement can be found at http://grants.nih.gov/grants/policy/policy.htm.

The PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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Department of Health and Human Services

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